

chlortetracycline hydrochloride troches proceed as directed in § 446.10a(b)(1) of this chapter, except § 446.10a(b)(1)(x), and in lieu of the directions in § 446.10a(b)(1)(iv) and (viii)(c) of this chapter prepare the sample as follows: Place 12 troches in a glass blending jar containing 500 milliliters of 0.01*N* HCl. Using a high-speed blender, blend for 3 to 5 minutes and then make the proper estimated dilutions in the buffer solution. The average potency of the troches is satisfactory if they contain not less than 85 percent of the number of milligrams they are represented to contain.

(b) *Moisture*. Proceed as directed in § 440.80a(b)(5)(i) of this chapter.

§ 436.514 Chlortetracycline hydrochloride powder topical; tetracycline hydrochloride powder topical.

(a) *Potency—(1) Dry powder*. Using a 3.0-gram sample or the entire contents of the immediate container for each determination, prepare the sample as follows: Using a high-speed blender, blend a 3.0-gram sample in a glass blending jar containing 500 milliliters of 0.01 *N* HCl (use 0.1 *N* HCl if it is tetracycline), or reconstitute in the immediate container as directed in the labeling of the drug. Transfer an appropriate aliquot of 1.0 milliliter to 5.0 milliliters to a 100-milliliter volumetric flask and make to mark with 0.01 *N* HCl (use 0.1 *N* HCl if it is tetracycline). Withdraw an aliquot from the volumetric flask, and if it is chlortetracycline hydrochloride dilute to 0.06 µg. per milliliter, using 0.1 *M* potassium phosphate buffer, pH 4.5, and proceed as directed in § 446.10a(b)(1) of this chapter. If it is tetracycline hydrochloride, dilute to 0.24 µg. per milliliter, using 0.1 *M* potassium phosphate buffer, pH 4.5, and proceed as directed in § 446.81a(b)(1) of this chapter. The average potency is satisfactory if it contains not less than 85 percent of the number of milligrams of chlortetracycline hydrochloride or tetracycline hydrochloride per gram or per immediate container that it is represented to contain.

(2) *Powder packaged with inert gases*. Spray, as directed in the labeling, the entire contents of each container to be tested into a separate 2-liter Erlen-

meyer flask, held in a horizontal position. Add 500 milliliters of 0.1 *N* HCl and shake to dissolve the contents. Immediately remove aliquots of this solution and, using 0.1 *M* potassium phosphate buffer, pH 4.5, for further dilutions, proceed as directed in § 446.10a(b)(1) of this chapter if it is chlortetracycline hydrochloride powder or § 446.81a(b)(1) of this chapter if it is tetracycline hydrochloride powder. Calculate the average total amount of antibiotic expelled from the containers. The total potency is satisfactory if it contains not less than 85 percent of the number of milligrams of chlortetracycline hydrochloride or tetracycline hydrochloride that it is represented to contain.

(b) *Moisture*. Proceed as directed in § 440.80a(b)(5)(i) of this chapter, except if it is packaged with inert gases proceed as directed in § 536.513(c) of this chapter.

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§ 436.515 Capsules tetracycline and oleandomycin phosphate; capsules tetracycline and troleandomycin; capsules tetracycline hydrochloride and oleandomycin phosphate; capsules tetracycline hydrochloride and troleandomycin.

(a) *Potency—(1) Tetracycline or tetracycline hydrochloride content by turbidimetric assay—(i) Test culture and media*. Maintain the test organism *Escherichia coli* (ATCC 10536)¹ on the agar described in § 440.80a(b)(1) (ii)(a) of this chapter. For use in the assay, prepare a suspension of the organism every 2 weeks, as follows: Transfer the organism to a fresh agar slant and incubate at 37°C. overnight. Wash the growth from the slant with the aid of 2 milliliters of sterile distilled water and sterile glass beads into a Roux bottle containing 300 milliliters of the maintenance medium. Incubate overnight at 37° C. and then harvest the growth with 50 milliliters of sterile distilled water and sterile glass beads. Standardize this suspension by determining the dilution that will permit 40-percent light

¹Available from: American Type Culture Collection, 12301 Parklawn Drive, Rockville, MD 20852.